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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/865,159	05/24/2001	Randall T. Irvin	113190-063	3428

7590 02/11/2002
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COPY OF PAPERS
ORIGINALLY FILED

EXAMINER	
GRASER, JENNIFER E	
ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 02/11/2002

DUE: 5-11-02

Please find below and/or attached an Office communication concerning this application or proceeding.

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DOCKET #: 113190-064

Office Action Summary

Application No.
09/865,159

Applicant(s)
Irwin et al.

Examiner
Jennifer Graser

Art Unit
1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Prel. Amendt. A.

2a) ☐ This action is FINAL.

2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 20 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 20 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4

20) ☐ Other:

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DETAILED ACTION

1. Acknowledgment and entry of the Amendment submitted 5/24/2001, Paper No. 3/A is made. Claim 20 is currently pending.

Claim Rejections - 35 USC § 112-Enablement

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 20 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are drawn to "a method for treating or preventing infection by *Pseudomonas aeruginosa* comprising administering a pharmaceutically acceptable amount of an isolated pilin peptide having the amino acid sequence set forth in SEQ ID Nos: 4, 6, 8 or 10", However, the instant specification only provides enablement for "methods of treating or preventing infection by *Pseudomonas aeruginosa* comprising administering a pharmaceutically acceptable amount of an isolated pilin peptide having the amino acid sequence set forth in SEQ ID Nos:2" as is claimed in allowed parent application US PAT 6,342,233. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

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The specification is only enabled for a method for treating or protecting against *P.aeruginosa* infection through the administration of K122-4 truncated pilin, i.e., a peptide comprising SEQ ID NO: 2. Additional evidences should be submitted to demonstrate the treatment or protective properties of SEQ ID NOS: 4, 6, 8 or 10. Example 5, pages 13-14, of the instant specification disclose that truncated pilin was administered to mice 15 minutes prior to their being challenged intraperitoneally with PAK. It is disclosed that percent survival was dose dependent within the range of pilin protein amounts tested. The results are shown in Figure 9. While this example may be sufficient to enable methods of treating or preventing infection by *P.aeruginosa* infection utilizing a peptide as set forth in SEQ ID NO:2, the specification does not provide enablement for a "method of treating or preventing infection by *P.aeruginosa* by administering an isolated peptide having the sequence identified by SEQ ID Nos: 4, 6, 8 or 10". The proteins set forth in SEQ ID NOS: 4, 6, 8 and 10 are completely different from the protein set forth in SEQ ID NO:2 and it is highly unpredictable whether or not these proteins would be able to prevent and/or treat *P.aeruginosa* infection. There are no challenge experiments provided in the specification which would enable the scope of these claims. Additional evidences should be submitted to demonstrate the protective properties of SEQ ID NOS: 4, 6, 8 or 10. Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the

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presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims. The nature of the invention is prevention of infection by *P.aeruginosa*. The prior art teaches that it extremely difficult and unpredictable to prevent *P.aeruginosa*. The instant specification only provides guidance and working examples for treatment and prevention using the peptide comprising SEQ ID NO:2. These results do not directly correlate to the proteins comprising SEQ ID Nos: 4, 6, 8 or 10 which comprise completely different structures. It would take undue experimentation to prevent or treat infection by *P.aeruginosa*. Challenge experiments would be required to enable methods of *prevention*. Given the lack of guidance contained in the specification, one of skill in the art could not make or use the broadly claimed invention without undue experimentation.

4. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15,1989). The Group 1641 Fax number is (703) 308-4242 which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (703) 308-1742. The examiner can normally be reached on Monday-Friday from 7:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

J. Graser 2/8/02
JENNIFER E. GRASER
PRIMARY EXAMINER